PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.:	10/618,223	Confirmation No.: 4411
Applicant(s):	Mangiardi et al.	
Filed:	07/11/2003	
Art Unit:	3736	
Examiner:	Kristin D. Rogers	
Title:	LUMEN-MEASURING DEVICES AND METHOD	

Docket No.: 047956/288167
Customer No.: 00826

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF UNDER 37 CFR § 41.37

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed January 24, 2007.

1. ***Real Party in Interest.***

The real party in interest in this appeal is Alveolus, Inc.

2. ***Related Appeals and Interferences.***

None.

3. ***Status of Claims.***

The present appeal involves Claims 1, 3-8, 10-24, 37, and 39-43, which are under final rejection as set forth by the Office Action mailed October 26, 2006. The claims at issue are set forth in the attached Claims Appendix.

4. ***Status of Amendments.***

Claim 43 has been cancelled subsequent to the final Office Action of October 26, 2006. The amendment to the claims is submitted in a separate paper and on the date of filing this Appeal Brief. Claims 1, 3-8, 10-24, 37, and 39-42 have not been amended following the final Office Action.

5. ***Summary of Claimed Subject Matter.***

Embodiments of the present invention provide devices that allow a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of a stenosis during the same exploratory surgery, as well as methods for measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis.

Independent Claims 1, 7, 24, and 37 each recite a device (100) that includes an exterior conduit (130) longitudinally extending between proximal and distal ends, wherein the exterior conduit has measurement markers (160) formed on a portion thereof (p. 8, lines 16-20; p. 10, lines 27-28; FIGS. 1, 2, 3, 7, and 14). Independent Claims 1, 7, 24, and 37 further recite that the device includes an interior conduit (180) longitudinally extending between proximal (190) and distal (200) ends, disposed within the exterior conduit (130), and displaceable with respect to the exterior conduit (p. 8, lines 16-23; p. 8, line 25 – p. 9, line 7; FIGS. 2, 4, 6, 8-10, 15, and 17). Independent Claims 1, 7, and 24 further recite that the interior conduit (180) includes a depth marking mechanism (210) visible through a portion of the exterior conduit (130) (p. 8, lines 23-25; p. 11, lines 19-23; FIG. 3, 4, 7, and 14-17).

In addition, independent Claims 1, 7, 24, and 37 recite a measurement assembly (240) including at least two legs (250, 300) having distal (260, 310) and proximal (270, 320) ends and inward facing (280, 330) and lumen facing (290, 340) surfaces, wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit (130) (p. 9, lines 8-18; p. 10, lines 16-26; FIGS. 5-13 and 16-18). In addition, the legs (250, 300) are coupled with each other proximal the distal ends (260, 310) thereof, and the measurement

assembly (240) is also coupled about the distal end (200) of the interior conduit (180) (p. 9, lines 8-14; FIGS. 2, 5-8, and 15-18).

Furthermore, independent Claims 1, 7, 24, and 37 recite a handle (220) that is operatively connected with the measurement assembly (240), wherein the handle includes means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration (p. 8, line 16 – p. 9, line 7; FIGS. 1-10 and 12-17).

Independent method Claims 7 and 24 also recite introducing the device (100) into an appropriate anatomical orifice of a patient, delivering the device adjacent to a target segment of a lumen within the patient, and measuring the length or diameter of the target segment of the lumen within the patient (p. 3, lines 5-21; p. 7, line 18 – p. 8, line 2).

6. ***Grounds of Rejection to be Reviewed on Appeal.***

Claims 1, 3-8, 10-24, 37, and 39-43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,919,147 to Jain in view of U.S. Patent No. 5,010,892 to Colvin et al.

7. ***Argument.***

Rejection of Claims 1, 3-8, 10-24, 37, and 39-43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Jain in View of Colvin

a) *The Cited References*

Jain discloses a vascular measuring device 10 including a sheath 22, a catheter 24, and a sensor 26, as shown in Figures 1-4. A proximal end 38 of the catheter includes graduated markings 42, while the distal end 40 supports the sensor 26. The sensor 26 includes several radially outwardly-biased filaments 44. When the catheter is retained within the sheath, the distal ends of the filaments bias outwardly to abut the interior of the sheath, as shown in Figure 2. When deployed from the sheath, the filaments of the sensor bias further outwardly to abut the interior of the blood vessel, as shown in Figure 3. In another embodiment, Jain discloses a

different sensor 54, as shown in Figures 5 and 6. The sensor 54 includes a pair of outwardly-biased arcuate arm springs 56 and 58. These springs are in a "longitudinally flat position" when in a retracted position within the sheath 22.

Colvin discloses a measuring instrument 10 having a sleeve 12, a handle 14 and a flexible cable 16 positioned within the sleeve, as shown in Figures 1 and 2. At a distal end of the flexible cable is a bifurcated probe having a memory for an outwardly curved shape when extended from the sleeve. A scale 24 is correlated to the deployment of the probe and provides a diameter measurement of a lumen. Ends of the bifurcated probes of the flexible cable each include a rounded ball at their distal ends.

b) Independent Claims 1, 7, 24, and 37

As indicated in the Brief Summary of Claimed Subject matter, each of independent Claims 1, 7, 24, and 37 recite a measurement assembly including at least two legs having distal and proximal ends and inward facing and lumen facing surfaces. The inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit. Thus, as shown in FIGS. 9 (side view) and FIG. 12 (end view), for example, each of the legs is flush along their entire length when the legs are positioned within the exterior conduit. In particular, FIG. 12 demonstrates that there may be four such legs in flush contact with one another according to one embodiment of the present invention.

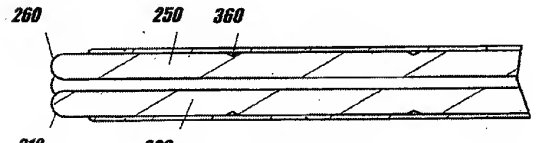


FIG. 9

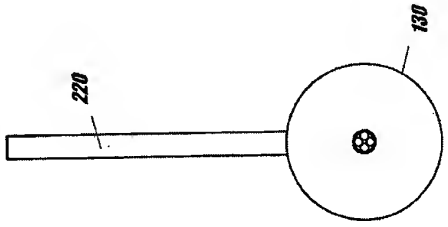


FIG. 12

c) The Rejection under 35 U.S.C. § 103(a) is Overcome

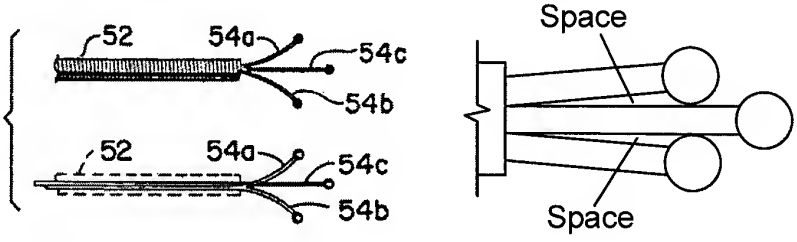
Neither Jain nor Colvin teaches or suggests at least two legs having inward facing surfaces that are in flush contact with one another from the distal ends of the legs to the proximal

ends of the legs when the measurement assembly is closed within the exterior conduit, as recited by independent Claims 1, 7, 24, and 37 of the present application. The Examiner relies on Colvin as disclosing this particular recitation by stating that:

> Colvin et al. teaches at least two legs having distal and proximal ends wherein the inward surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed with in [sic] the exterior conduit. The Examiner notes that Colvin et al. discloses that the embodiment of Figure 5, although not illustrated, is constructed as such the two legs 54a and 54b will merge into a single cable which fairly suggests the two legs being in flush contact with one another from the distal to proximal ends (column 4, lines 15-20).

Applicants respectfully disagree, as FIG. 5 of Colvin discloses that each of the bifurcated probes of the cable includes a rounded ball at their respective distal ends. Thus, the balls at the ends of each of the probes would prevent the portions from lying substantially flush against each other from their proximal to their distal ends when being retracted within an exterior conduit. The non-congruent surfaces of the balls would prevent the probes from being in flush contact between their proximal and distal ends. In this regard, Applicants have provided a sketch that clearly illustrates that the balls at the ends of the probes would prevent the probes from being flush with one another between their proximal and distal ends, as there would at least be a space between the portions proximate to their distal ends.

FIG. 5



In addition, the Examiner finds that:

> Broadly interpreted, the proximal end of the legs may be considered to be the terminal point at the proximal-most end of each leg and a portion distal to the proximal end of the legs may be considered to be a point distal, but immediately adjacent. The distal end of Colvin et al. is considered the region extending the length of element (12 or 52) while the rounded balls (16 or 54a or 54b) are located at the tip.

However, independent Claims 1, 7, 24, and 37 recite that the legs are in flush contact from the distal ends of the legs to the proximal ends of the legs. Applicants refer the Examiner to FIG. 9 shown above, where the distal ends (260, 310) are clearly at the ends of the legs, not at some arbitrary point distal the proximal end, as suggested by the Examiner. Thus, the claimed invention and specification of the present application clearly demonstrate that the legs are in flush contact along the entire length of the legs between their proximal and distal ends, not at some point distal of the proximal end. Allowing the legs to be in flush contact along their entire length reduces the diameter of the exterior conduit required to house the legs, which, for example, allows the device to be positioned in a narrow lumen or a working channel of an optical scope. And, as discussed above, the balls at the ends of the probes of Colvin would prevent the probes from being in flush contact between the proximal and distal ends of the probes, which is unlike independent Claims 1, 7, 24, and 37.Although not specifically relied upon by the Examiner in rejecting the recitation of independent Claims 1, 7, 24, and 37 discussed above, Applicants also note that Jain does not teach or suggest at least two legs having inward facing surfaces that are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit. In contrast, the sensor of Jain includes several radially outwardly-biased filaments 44 that fan outwardly when the sensor is retained within the sheath and are not in flush contact between their proximal and distal ends. The embodiment of Jain shown in Figure 5 also shows that there is a significant gap between the arm springs when retained within the sheath. Thus, neither of the embodiments of Jain discloses the arm springs or filaments lying substantially flush against each other from their proximal to their distal ends when being retracted within an exterior conduit, which is unlike the claimed invention.

d) The Previous Examiner Conceded that Claims of the Present Scope are Distinguishable from Colvin and Jain

The present application was initially examined by Examiner Marmor. In the Office Action dated March 16, 2006, Examiner Marmor stated that "the Examiner concedes that neither Jain nor Colvin et al. teach an arrangement where the entire length of the inward facing surfaces of the legs are in flush contact as recited in claim 43." Dependent Claim 43 (now cancelled)

recited that the portion of the inward facing surfaces in flush contact extends distally from the proximal ends to the distal ends of the legs. The scope of Claim 43 was substantially similar to the scope recited by current independent Claims 1, 7, 24, and 37.

The final Office Action was issued by Examiner Rogers. In the final Office Action, Examiner Rogers found that independent Claims 1, 7, 24 and 37 were unpatentable over the combination of Colvin and Jain and, thus, completely changed positions with respect to Examiner Marmor's conclusion. Furthermore, it appears that Examiner Rogers simply copied Examiner Marmor's previous rejection when stating that "[t]he inward facing surfaces along a portion of the legs are in flush contact with one another along a portion distal of the proximal ends when the measurement assembly is closed." (emphasis added). However, this particular portion of independent Claims 1, 7, 24 and 37 was amended as set forth in Applicant's response of June 15, 2006 (which represents the current version of the claims under appeal) and the claims no longer recite that the flush contact is only along a portion of the legs.

Since the only rejection remaining is the combination of Colvin and Jain, independent Claims 1, 7, 24 and 37 should have been in condition for allowance based on Examiner Marmor's previous findings. Under MPEP § 706.04:

> Full faith and credit should be given to the search and action of a previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general, an examiner should not take an entirely new approach or attempt to reorient the point of view of a previous examiner, or make a new search in the mere hope of finding something.

Examiner Rogers did not specifically address why the prior indication of allowable subject matter was reversed in light of Colvin and Jain and, thus, did not present any evidence as to why Examiner Marmor's point of view should be changed. Moreover, the Examiner appears to have failed to closely read Applicant's amendments when setting forth the rejections in the final Office Action and provide a complete and clear action (see MPEP § 707.07).

Therefore, Applicant submits that the rejection of independent Claims 1, 7, 24, and 37 under 35 U.S.C. § 103(a) is overcome. Because each of the dependent claims includes the recitations of a respective independent claim, the dependent claims are allowable for at least those reasons discussed above with respect to independent Claims 1, 7, 24, and 37.

CONCLUSION

For the above reasons, it is submitted that the rejections of the pending claims are erroneous and reversal of the rejections is respectfully requested. A Claims Appendix containing a copy of claims involved in the appeal, an Evidence Appendix, and a Related Proceedings Appendix are attached.

Respectfully submitted,

Trent A. Kirk
Registration No. 54,223

Customer No. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Charlotte Office (704) 444-1000
Fax Charlotte Office (704) 444-1111

ELECTRONICALLY FILED USING THE EFS-WEB ELECTRONIC FILING SYSTEM OF THE UNITED STATES PATENT & TRADEMARK OFFICE ON March 26, 2007.

Claims Appendix.

1. (Previously Presented) A device that allows a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the same exploratory procedure, the device comprising:

an exterior conduit longitudinally extending between proximal and distal ends, the exterior conduit having measurement markers formed on a portion thereof;

an interior conduit longitudinally extending between proximal and distal ends, disposed within the exterior conduit, and displaceable with respect to the exterior conduit, the interior conduit having a depth marking mechanism visible through a portion of the exterior conduit;

a measurement assembly comprising at least two legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the distal end of the interior conduit;

a handle operatively connected with the measurement assembly, the handle comprising a means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration.

2. (Cancelled)

3. (Previously Presented) The device of claim 1, wherein when the measurement assembly is moved distally in relation to the exterior conduit, the legs form an acute angle with respect to one another.

4. (Original) The device of claim 3, wherein the measurement assembly further comprises a third leg.

5. (Previously Presented) The device of claim 1, wherein the distal ends of the legs are coupled together, wherein measurement of the target site takes place between the distal and proximal ends of the legs.

6. (Previously Presented) The device of claim 1, wherein the handle further comprises a measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between a first and second handle location.

7. (Previously Presented) A method of measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis, the method comprising:

providing a measuring device having an exterior conduit longitudinally extending between proximal and distal ends, the exterior conduit having measurement markers formed on a portion thereof; an interior conduit longitudinally extending between proximal and distal ends, disposed within the exterior conduit, and displaceable with respect to the exterior conduit, the interior conduit having a depth marking mechanism visible through a portion of the exterior conduit; a measurement assembly comprising at least two legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs

when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the distal end of the interior conduit; a handle operatively connected with the measurement assembly, the handle comprising a means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration;

introducing the device into an appropriate anatomical orifice of a patient;

delivering the device adjacent a target segment of a lumen within the patient; and

measuring the length of the target segment of the lumen within the patient.

8. (Original) The method of claim 7, wherein the device further comprises an optical scope operatively coupled therewith, such that the measuring step is accomplished using the optical scope.

9. (Cancelled)

10. (Previously Presented) The method of claim 7, wherein when the measurement assembly is moved distally in relation to the exterior conduit, the legs form an acute angle with respect to one another.

11. (Original) The method of claim 10, wherein the measurement assembly further comprises a third leg.

12. (Previously Presented) The method of claim 7, wherein the distal ends of the legs are coupled together, wherein measurement of the target site takes place between the distal and proximal ends of the legs.

13. (Previously Presented) The method of claim 7, wherein the handle further comprises a measurement indicator, wherein target lumen dimensions are calculated based on the

relative distance the handle travels along the continuum between a first and second handle location.

14. (Original) The method of claim 7, further comprising the step of measuring the diameter of the target segment of the lumen within the patient.

15. (Previously Presented) The method of claim 14, wherein the diameter measuring step comprises the step of actuating the handle along the continuum from the first closed configuration toward the second open configuration until the legs of the measurement assembly come in contact with the target segment of the lumen and calculating the length as a function of the number of leg measurement markings distal the exterior conduit.

16. (Original) The method of claim 14, wherein the target segment of the lumen is stenotic.

17. (Previously Presented) The method of claim 7, wherein the device further comprises an optical scope operatively coupled therewith, such that the measuring step is accomplished using the optical scope to view placement of the measurement assembly.

18. (Original) The method of claim 16, further comprising the step of measuring the length of the stenosis.

19. (Original) The method of claim 18, wherein the delivering step further comprises the step of positioning the distal end of the first conduit distal the stenosis.

20. (Previously Presented) The method of claim 19, wherein the measurement assembly is opened and placed distal the stenosis such that the exterior conduit is retracted and the stenosis length measurement is a function of the distance the exterior conduit is retracted proximally.

21. (Original) The method of claim 18, wherein the stenosis length measuring step comprises the step of actuating the handle along the continuum from the first closed configuration toward the second open configuration until the legs of the measurement mechanism come in contact with the target segment of the lumen and calculating the length as a function of the distance between the first handle position and the current point of the handle along the continuum.

22. (Original) The method of claim 16, further comprising the step of measuring the height of the stenosis.

23. (Original) The method of claim 22, further comprising the step of measuring the length of the stenosis.

24. (Previously Presented) A method of measuring a target segment of a lumen of a patient so as to select a suitable interventional prosthesis, the method comprising:

providing a measuring device having an exterior conduit longitudinally extending between proximal and distal ends, the exterior conduit having measurement markers formed on a portion thereof; an interior conduit longitudinally extending between proximal and distal ends, disposed within the exterior conduit, and displaceable with respect to the exterior conduit, the interior conduit having a depth marking mechanism visible through a portion of the exterior conduit; a measurement assembly comprising four legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to proximal ends of the legs when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the distal end of

the interior conduit; a handle operatively connected with the measurement assembly, the handle comprising a means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration;

introducing the device into an appropriate anatomical orifice of a patient;

delivering the device adjacent a target segment of a lumen within the patient; and

measuring the diameter of the target segment of the lumen within the patient.

25-36. (Cancelled)

37. (Previously Presented) A device that allows a user to calculate the length and diameter of a suitable interventional prosthesis as well as the height and length of stenosis during the some exploratory procedure, the device comprising:

an exterior conduit longitudinally extending between proximal and distal ends, the exterior conduit having measurement markers formed on a portion thereof;

an interior conduit longitudinally extending between proximal and distal ends, disposed within the exterior conduit, and displaceable with respect to the exterior conduit;

a measurement assembly comprising a plurality of legs having distal and proximal ends and inward facing and lumen facing surfaces wherein the inward facing surfaces of the legs are in flush contact with one another from the distal ends of the legs to the proximal ends of the legs when the measurement assembly is closed within the exterior conduit, the legs coupled with each other proximal the distal ends thereof, the measurement assembly also coupled about the distal end of the interior conduit;

a handle operatively connected with the measurement assembly, the handle comprising a means for opening and closing the measurement assembly by actuating the handle along a continuum between a first closed configuration and a second open configuration.

38. (Cancelled)

39. (Previously Presented) The device of claim 37, wherein when the measurement assembly is moved distally in relation to the exterior conduit, the legs form an acute angle with respect to one another.

40. (Original) The device of claim 39, wherein the measurement assembly comprises four legs.

41. (Previously Presented) The device of claim 37, wherein the distal ends of the legs are coupled together, wherein measurement of the target site takes place between the distal and proximal ends of the legs.

42. (Previously Presented) The device of claim 37, wherein the handle further comprises a measurement indicator, wherein target lumen dimensions are calculated based on the relative distance the handle travels along the continuum between a first and second handle location.

43. (Cancelled)

Evidence Appendix.

None.

Related Proceedings Appendix.

None.